

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>Applicant:</b> Copa et al.	<b>Examiner:</b> Yabut, Diane D.
<b>Serial No.</b> 10/646,383	<b>Group Art Unit:</b> 3734
<b>Filed:</b> August 21, 2003	
<b>For:</b> ANASTOMOSIS DEVICE AND RELATED METHODS	<b>Docket No.</b> AMS0008/US

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY BRIEF**

Dear Madam:

This Reply Brief is being submitted in response to the Examiner's Answer mailed on March 23, 2011, in the above-identified patent application, which is under appeal.

The Reply Brief is believed to be timely filed with the two-month period set out in M.P.E.P § 1208 from the date of the Examiner's Answer.

No fee is believed to be due at this time. If any fees are required, please charge them to Deposit Account No. 50-1775 and notify us of the same.

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### **I. Status of Claims**

Claims 1-9, 11-14, and 26-44 are pending.

Rejected claims: 1-9, 11-14, and 26-44

Allowed claims: none.

Withdrawn claims: none.

Objected to claims: none.

Canceled claims: 10 and 15-25

Appealed claims: 1-9, 11-14, and 26-44

## **II. Grounds of Rejection to be Reviewed on Appeal**

**A.** Whether claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are anticipated by Sharkey et al. (U.S. Patent 5,540,701).

**B.** Whether claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are unpatentable over Sharkey et al. (U.S. Patent 5,540,701) in view of Kirsch et al. (U.S. Patent 6,461,367).

### **III. Argument**

A. Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35 U.S.C. §102(b) as being anticipated by Sharkey et al. (U.S. Patent 5,540,701).

These rejections are traversed for reasons of record as set out within Appellants' Appeal Brief and additionally in response to certain points raised by the Examiner within the Examiner's Answer dated March 23, 2011 as follows.

The prosecution of record is premised on the flawed argument that the balloon of the Sharkey reference is "elongate," and therefore is an "elongate tissue approximating structure" as recited in certain of Applicant's claims.

The term elongate is well understood in accordance within its normal and ordinary meaning as an adjective modifier of an element to have a significantly longer length than width. Meaning, such an element must look long and narrow. Moreover, in accordance with these same claim limitations, it is recited that the elongate tissue approximating structure has the capability of being extended and retracted from the catheter body wall. Read together, it is clear that what is claimed is a long and narrow (elongate) element that is provided as structure having the ability to extend from the catheter wall. As an elongate element that has a length of extent, it is necessary that this extension be in the direction of its length. To be otherwise would render the element non-elongate. The claimed elongate structure is recited as having the ability to extend and retract from the catheter body, as such extension and retraction is based upon the long and narrow shape of the elongate structure.

In attempting to read the Sharkey et al reference on these limitations of certain pending independent claims, the Examiner relies upon the two-balloon structure (32 and 36) of the disclosed catheter. Specifically, the balloons of the Sharkey et al reference are noted as being able to impart various geometrical configurations to expand the portions 12 and 14 of the fixation device 10.

In looking at the disclosed balloons of the Sharkey et al reference, it is clear that they are typical expandable catheter balloons that expand under pressure to provide a controlled expansion of portions of a wire frame device, such as fixation device 10. Such balloons can be shaped, as noted, for shaping the device as implanted. To the extent that such balloons are

elongate, it is also clear that in the non-inflated state they are longer in the direction of extension of the catheter body than they are wide in the transverse direction perpendicular to the extension of the catheter body. The non-inflated state would correspond to a position of the elongate structure from which the elongate structure can be extended and retracted from the catheter body wall, as presently claimed. However, in direct contrast to the presently claimed invention, the balloons 32 and 36 can each be inflated to extend in the direction of their respective width direction.

The Examiner has taken the position that the balloons of the Sharkey et al reference read on the elongate structure since the balloons "exhibit a length when deflated or inflated or are drawn out to a greater length when inflated." The balloons exhibit a length when deflated in the direction of the extension of the catheter, as above. When inflated, this length stays the same. The width of the balloons, as may be shaped with various geometries, is expanded or lengthened by inflation. It is certainly possible that the expansion in the width direction can be greater than the length of a non-inflated balloon, but it is not contemplated to expand such a balloon to the extent of defining an inflated elongate structure that looks long and narrow in any way (see Fig. 13, for example). The elongate structure is defined at the state where an elongate structure can be expanded and then retracted, not at the expanded or extended state. As such, the Sharkey et al reference lacks any elongate structure (long and narrow) that can be extended from the catheter wall, as claimed. Reversal of the Examiner's reading of the balloons of the Sharkey et al reference on the claimed elongate tissue approximating structure is believed to be proper and is again respectfully requested.

Additionally, Appellants reassert that the subject specification clearly distinguishes the use of expandable balloons from the claimed elongate structure. In particular, the description of the claimed elongate structure excludes a balloon, based on the content of Applicant's patent specification. This is regardless of the fact that the a balloon, as disclosed within the Sharkey et al reference could not be read upon an elongate structure that can extend and then retract with respect to a catheter body, as above. In this regard, the Examiner remains silent. At one point in responding to Appellants' arguments in general, the Examiner notes that limitations from the specification are not read into the claims. To this, Appellants agree. However, where a term is clearly set up within the specification as including certain type structure and specifically excluding other structure, and that terminology is chosen in particular for the claims, it is

apparent that the excluded structure is distinct. Moreover, for the many reasons also stated above, such a distinction is based upon the actual structural shape and functionality of the claimed elongate structure. Accordingly, reversal of these rejections of record based upon the Sharkey et al reference is also believed to be proper and respectfully requested.

**B.** Claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (U.S. Patent 5,540,701) in view of Kirsch et al. (U.S. Patent 6,461,367).

These claims depend on independent claim 1, 9, or 26, and, therefore, require the tissue approximating structure features of those independent claims, including at least one "elongate" tissue approximating structure.

These grounds of rejection of record are traversed for all of the reasons asserted within Appellants' Brief and additionally as follows.

The rejection of record lacks any legally sound reason why one of skill would have replaced the balloon of Sharkey with the tines of Kirsch, where the offered reasoning is based on information found in the cited prior art references taken as a whole and without the benefit of Applicant's own disclosure.

In responding to Appellants' arguments, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to modify the balloons 32 and 36 of the device of the Sharkey et al reference with the structures 30 of the Kirsch et al reference to selectively expand/retract the tissue approximating members. To clarify what is meant as the tissue approximating members, the Examiner goes on to state that the Sharkey et al reference also teaches that "distensible members that are mechanically extended and retracted in order to deploy the proximal and distal ends 12 and 14" may be used. Meaning that Sharkey et al contemplate other devices (including mechanical means) than a balloon can be used to expand the portions 12 and 14 of the fixation device so that the device is engaged into surrounding tissue.

A problem with the combination of the Sharkey et al reference with the Kirsch et al reference as suggested by the Examiner and based upon the above logic is that the Kirsch et al reference fails to disclose any mechanical or other device or structure that is used to expand any type of device into place within tissue. The prongs 30 of the Kirsch et al device are not similar

to nor functionally equivalent to the balloons 32 and 36 of the Sharkey et al reference. These prongs 30 merely evert the open ends of the urethra and bladder tissue so that a clip can be applied by a surgeon for holding the urethra to the bladder.

One of ordinary skill in the art would not have looked to a tissue everting prong as a means for expanding a device into tissue fixation. These dissimilar structures are provided for different purposes and with such different functionality that one of ordinary skill in the art would not have looked to the prongs 30 of the Kirsch et al reference in attempting to modify the balloons of the Sharkey et al reference with a different means to expand its fixation device portions 12 and 14. There is no reason to even believe that such would work for such purpose. The Examiner asserts that the prongs 30 could be provided instead of balloons to expand the fixation device portion 12 and 14, but there is no reason or specific logic asserted to conclude that such prongs could even perform the necessary functionality at all.

Moreover, if such a substitution were somehow supported and made, it is submitted that expansion prongs are not tissue approximating structure as claimed, the purpose of which is to itself engage with the relevant tissue for holding the claimed anastomosis device in place according to the present invention. There is simply no reason to try and combine the prongs 30 with the device of the Sharkey et al reference. Accordingly, reversal of the rejections of record based upon the Sharkey et al reference in combination with the Kirsch et al reference is also respectfully requested.



**Conclusion**

In view of these remarks, it is respectfully submitted that pending claims 1-9, 11-14, and 26-44 are in condition for allowance. Accordingly, it is respectfully submitted that the rejections of the claims under 35 U.S.C §§ 102 and 103 be withdrawn on this appeal.

Respectfully Submitted,

Dated: May 23, 2011

By: 

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#### IV. Appendix – Claims on Appeal

1. An anastomosis device comprising
  - a hollow, elongate, flexible catheter body having a proximal end and a distal end,
  - the distal end comprising a catheter body wall,
  - an inflatable balloon at the distal end,
  - a drainage aperture at the distal end, and
  - elongate tissue approximating structure that can be extended and retracted from the catheter body wall at the distal end of the catheter body on a proximal side of the inflatable balloon,wherein the inflatable balloon is on a proximal side of the drainage aperture.
2. The device of claim 1 wherein, when the device is installed in a body having a prostate removed, with the balloon in the bladder, the tissue approximating structure is capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue, and combinations of these.
3. The device of claim 1 wherein the tissue approximating structure comprises movable elongate structure selected from a tine, a probe, a prod, and a needle.
4. The device of claim 3 wherein the tissue approximating structure can be extended and retracted from apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.
5. The device of claim 1, comprising
  - an inflation lumen extending from the proximal end to the balloon,
  - a drainage lumen extending from the drainage aperture at the distal end to a port at the proximal end, and
  - movable elongate tissue approximating structure positioned to extend through apertures in the hollow catheter body at the distal end.

6. The device of claim 1, comprising
  - an inflation lumen extending from the proximal end to the balloon,
  - a drainage lumen extending from the drainage aperture at the distal end to a port at the proximal end, andwherein the tissue approximating structure comprises
  - distal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the balloon, and
  - proximal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the distal tissue approximating structure.
7. The device of claim 1 wherein the tissue approximating structure comprises multiple tines.
8. The device of claim 1 wherein the tissue approximating structure comprises multiple opposing tines.
9. An anastomosis device comprising
  - a hollow elongate flexible catheter body having a proximal end and a distal end, the distal end comprising a catheter body wall,
  - an inflatable balloon at the distal end and inflation means to inflate the balloon,
  - a drainage aperture and drainage means connected to the drainage aperture for draining urine from a bladder, and
  - elongate tissue approximating means on the proximal side of the balloon for holding severed tissue in contact for healingwherein the inflatable balloon is on a proximal side of the drainage aperture and the tissue approximating means can be extended and retracted from the catheter body wall at a location along the distal end of the catheter body.
10. (canceled)

11. The device of claim 9 further comprising actuating means for actuating the tissue approximating means, the actuating means connected to the tissue approximating means and extending from the tissue approximating means to the proximal end.
12. The device of claim 9 wherein the tissue approximating means is selected from the group consisting of an inflatable balloon, a movable elongate structure, and a combination thereof.
13. The device of claim 9 wherein the tissue approximating means comprises a movable tine.
14. The device of claim 9 wherein, with the device positioned to place the at least a portion of the catheter body inside the urethra and the inflated balloon in the bladder, the tissue approximating means can be extended to contact tissue selected from the group consisting of bladder tissue, urethral tissue, urethral stump tissue, and perineal wall tissue.
- 15-25. (canceled)
26. An anastomosis device comprising
  - a hollow, elongate, flexible catheter body having a proximal end and a distal end, the distal end comprising a catheter body wall,
  - a drainage aperture at the distal end, and
  - tissue approximating structure at the distal end of the catheter body, the tissue approximating structure comprising first tissue approximating structure and second tissue approximating structure, the first and second tissue approximating structure located on a proximal side of the drainage aperture, wherein each of the first and second tissue approximating structure can be extended and retracted from the catheter body wall, and the second tissue approximating structure comprises elongate structure.
27. The device of claim 26 wherein, when the device is positioned to place a distal portion of the catheter body inside the urethra, the first tissue approximating structure can be located to contact tissue of the bladder and the second tissue approximating structure is located to contact

tissue selected from tissue of a bladder, tissue of a perineal wall, urethral stump tissue, tissue inside a urethra and combinations of these.

28. The device of claim 27 wherein the first tissue approximating structure is selected from the group consisting of a balloon and a balloon-like structure.

29. The device of claim 28 wherein the first tissue approximating structure, when placed inside of the bladder, is capable of expanding within the bladder to prevent urine from passing through the bladder neck and urethra to an anastomosis site.

30. The device of claim 27 wherein the second tissue approximating-structure is located on a proximal side of the first tissue approximating structure, and the second tissue approximating structure comprises movable elongate structure selected from a tine, a probe, a prod, and a needle.

31. The device of claim 30 wherein the second tissue approximating structure comprises multiple opposing tines.

32. An anastomosis device comprising  
a hollow, elongate, flexible catheter body having a proximal end and a distal end,  
the distal end comprising a catheter body wall,  
a drainage aperture at the distal end,  
an inflatable balloon at the distal end on a proximal side of the drainage aperture,  
tissue approximating structure that can be extended through apertures in the  
catheter body wall, at the distal end of the catheter body on a proximal side of the inflatable  
balloon, the tissue approximating structure comprising movable elongate structure selected from  
a tine, a probe, a prod, and a needle.

33. The device of claim 32 wherein the tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

34. The device of claim 32 comprising

distal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the balloon, and

proximal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the distal tissue approximating structure,

wherein the distal tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end, and

wherein the proximal tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

35. The device of claim 1 wherein tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and wherein

the balloon can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

36. The device of claim 35 wherein the tissue approximating structure comprises multiple tines.

37. The device of claim 1 wherein the tissue approximating structure comprises

distal tissue approximating structure comprising multiple tines, and

proximal tissue approximating structure comprising multiple tines that oppose the multiple tines of the distal tissue approximating structure,

wherein the distal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and the proximal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

38. The device of claim 37 wherein the position of the balloon on the catheter body is fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

39. The device of claim 9 wherein tissue approximating means can be extended and retracted from the catheter body wall at a fixed location along the distal end of the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

40. The device of claim 39 wherein the tissue approximating means comprises multiple tines.

41. The device of claim 9 wherein tissue approximating means comprises  
distal tissue approximating means comprising multiple tines, and  
proximal tissue approximating means comprising multiple tines that oppose the multiple tines of the distal tissue approximating means,  
wherein the distal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and the proximal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

42. The device of claim 41 wherein the position of the balloon on the catheter body is fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

43. The device of claim 26 wherein the first approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and  
the second tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

44. The device of claim 43 wherein the first tissue approximating structure comprises an inflatable balloon and the second tissue approximating structure comprises multiple tines.